IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/699,212	Confirmation No.:	2780
Applicant	:	David R. Hennings et al.		
Filing Date	:	October 30, 2003		
Title	:	Endovenous Closure of Varicose Veins with Mid-Infrared Laser		
Group Art Unit	:	3769		
Examiner	:	David M. Shay		
Docket No.	:	15487.4002		
Customer No.	:	34313		

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REQUEST TO REOPEN PROSECUTION UNDER 37 C.F.R. 1.111 AND RESPONSE TO NEW GROUND OF REJECTION IN EXAMINER'S ANSWER

I. INTRODUCTION

The Examiner's Answer dated Nov. 13, 2008, in this application states, at page 4, a new ground of rejection of claims 26-34 as unpatentable over Goldman in view of Sinofsky and Dew et al. Applicants request that prosecution be reopened under 37 C.F.R. 1.111. This request is accompanied by a response to the new ground of rejection and the declarations of two of the inventors named in this application, David R. Hennings and Mitchel P. Goldman. These declarations support the following remarks.

II. REMARKS

The principal reasons why the rejection of claims 26-34 is in error are:

(a) Goldman does not enable the use of lasers.

(b) Sinofsky and Dew cannot be properly combined with Goldman.

(c) The scientific literature which taught that the use of the laser wavelengths above 1064 nm, such as the wavelengths of 1200-1800 nm claimed in the present application, was undesirable and presented risks to the patient is representative of the prior art and the state of the art as it existed prior to the present invention.

(d) It is only Navarro Patent No. 6,398,777, which uses laser wavelengths of 500-1100 nm, not the present invention, which could be considered a "predictable use of the prior art".

(e) Consistent with Navarro, prior to the present invention, all other prior art products involving the use of lasers to treat varicose veins used wavelengths in the range of 810-1064 nm.

Goldman does not enable the use of lasers to treat varicose veins

The Goldman patent makes only a single mention of lasers as an alternative to the use of radio frequency (RF) energy and it is plain that the focus of the patent is on the use of tumescent anesthetic with known RF modes of treatment. This is confirmed in paragraphs 3-5 of the Goldman declaration.

As stated in the Goldman Declaration, paragraph 5, submitted herewith, the only work done with regard to the subject matter of Goldman Patent No. 6,258,084 was with regard to RF devices not lasers and the people doing that work had no experience or knowledge which would permit them to enable the use of lasers to treat varicose veins. Among the requirements for ennoblement which were not known were the laser wavelengths which might be useful and the power levels needed for safe and effective treatment.

In this regard, it is important to keep in mind the fundamental difference between heating with laser energy as compared with other types of thermal energy, e.g., RF, direct current, circulating heated fluid, etc., as disclosed at col. 7, lines 54-59 of Goldman. Those other types of thermal energy involve

transferring heat from a heated element to the material it is desired to heat. This type of heating results in heat being transferred to anything in the proximity of the heat source.

Laser heating, on the other hand, is selective. Different types of lasers operate over a wide spectrum of wavelengths and, in order to heat a target material, a laser and its wavelength must be chosen to selectively heat that target material, i.e., the target material must be a chromophore for that wavelength. Thus, the target must be chosen before the wavelength can be selected.

Accordingly, in order to enable laser treatment of varicose veins, a precondition would be the selection of the target material. None of this is disclosed in Goldman.

In paragraph 6 of his declaration, Goldman states that it was Navarro who made the first attempt known to him to develop a laser-based treatment for varicose veins, but that Navarro took a wrong path in his choice of wavelengths. The reasons why this was a wrong choice are spelled out in Exhibits A, B and C to the Geriak Declaration filed in this application and, as stated in paragraph 8 of the Goldman declaration, those scientific literature articles are representative of the belief held in the art prior to the invention of the present application.

Thus, the Goldman patent cannot be considered to enable the use of lasers for the treatment of varicose veins, much less the use of the wavelengths recited in the claims of the present application. Furthermore, the Navarro patent and Exhibits A, B and C to the Geriak Declaration demonstrate that applicant's choice of wavelengths was unobvious.[1]

[1] In spite of this lack of enablement, VNUS has sued CoolTouch and others for infringement of Patent Nos. 6,258,084; 6,752,803; 6,769,433; 7,396,355 and 7,406,970 in VNUS v. Biolitec et al., Case No. C08-03129 MMC, in the Northern District of California.

Sinofsky and Dew cannot be properly combined with Goldman

The reasons why Sinofsky and Dew cannot be properly combined with Goldman have been spelled out in our Appeal Brief, which is incorporated here by reference. In brief, Sinofsky is directed to opening up blood vessels, not, as is the present invention, to closing them down. Dew is far afield and is concerned with wound healing and has absolutely nothing to do with the treatment of blood vessels. The notion that one skilled in the art of treating varicose veins would have looked to either for guidance in devising a laser treatment for varicose veins is, on its face, farfetched. More importantly, it is plain beyond any doubt that what those skilled in the art **did do** is completely at odds with the Examiner's thesis. What those in the art actually did is reflected in the Navarro patent and in Exhibits A-E attached to the Hennings declaration filed on July 5, 2005, i.e., the use of laser wavelengths in the range of 500-1100 nm, and more particularly, in the range of 810-980 nm, **not the wavelengths of Sinofsky or Dew.**

The Examiner's reliance (page 10 of the Examiner's Answer) on KSR International v. Teleflex, Inc., 127 S.Ct. 1727, 82 USPQ2d 1385 (2007) is badly misplaced. The PTO Board of Appeals, in post KSR decisions, has cited KSR for the proposition that there must be reasoning supported by rational underpinning to support an obviousness rejection. For example, in Ex parte Crawford, Appeal 20062429, Decided May 30, 2007, the Board said:

> "We find no suggestion to combine the teachings of [the prior art] as advanced by the Examiner, except from using Appellants' invention as a template through a hind sight reconstruction of Appellants' claims."

So, as we have demonstrated above, it is here. In this regard, we note that KSR cites with approval the decision In re Kahn, 44a F.3d 977, 988 (Fed. Cir. 2006) which holds that:

> "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

In the present case, all we have from the Examiner are conclusory statements, e.g., the bare conclusory statement at page 9 of the Examiner's Answer that Goldman enables the treatment of varicose veins with lasers which relies **only** on disclosures relating to RF treatment in Goldman and then lurches to an entirely irrelevant discussion of Sinofsky and Dew, followed by an entirely unsupported conclusion of enablement. We now, of course, have the declaration of Goldman which states that the Examiner's unsupported conclusion regarding enablement is also wrong.

Similarly, the attempted combination of Goldman with Sinofsky has no rational underpinning. Keeping in mind that Goldman has zero to say about what the target chromophore of a laser to be used for treating varicose veins should be, i.e., blood, vein tissue, or some other, the Examiner attempts to combine Sinofsky, who has a totally different target, plaque in a vein lumen. The laser wavelengths used according to the present invention target the water in the vein wall, a target mentioned by neither Goldman nor Sinofsky. Goldman wants to destroy the functionality of a vein whereas Sinofsky wants to preserve and improve that functionality. There is absolutely no rational underpinning for this combination.

The additional reliance on Dew makes things even worse. The wound healing method of Dew is far removed from the varicose vein treatment of Goldman and far removed from the plaque removal treatment of Sinofsky. The Examiner's statement that because the wavelengths of Dew are "useful" (page 10) for an unrelated purpose, their use in treating varicose veins would obvious is a bare and baseless conclusory statement.

Furthermore, the scientific literature, as shown in Exhibits A, B and C to the Geriak Declaration, **taught against** the use of the wavelengths of Sinofsky and Dew in the treatment of varicose veins.

Thus, it can only be the teachings of the present application which prompts the Examiner's attempt to patch together the unrelated teachings of Sinofsky and Dew with Goldman.

Exhibits A, B and C to the Geriak Declaration are representative of the prior art.

As stated in paragraphs 3-9 of the Hennings declaration filed herewith and paragraph 8 of the Goldman Declaration, Exhibits A, B and C to the Geriak Declaration are representative of the prior art as it existed prior to the present invention. That this is so is confirmed by the Fan/Rox-Anderson article attached as Exhibit 1 to the Hennings Declaration filed herewith, which cites the Proebstle articles which are Exhibits B and C to the Geriak Declaration in footnotes 7 and 14.

The importance of the Fan/Rox-Anderson article is great. It is a fairly recent survey article authored by a preeminent physician in the art to which the present invention relates and is published in a very respected journal. This article traces the history of energy based treatment of varicose veins in several stages progressing from (a) RF heating to (b) the laser heating of Navarro to (c) the laser heating of the present invention. This is the real world.

The Examiner's excursion into the unrelated teachings of Sinofsky and Dew is nothing less than the creation of an imaginary alternate universe which has no basis in fact and no rational underpinnings. Similarly, the Examiner's refusal to recognize Navarro as more relevant prior art than the unsustainable combination of Goldman, Sinofsky and Dew defies comprehension.

Thus, the Goldman and Hennings declarations and the Fan/Rox-Anderson article refute the Examiner's position to the contrary.

The Significance of the Navarro Patent

The citation of the Navarro patent in footnote 15 of the Fan/Rox-Anderson article is strong confirmation of the fact that the move from RF treatment to laser treatment of varicose veins involved a choice of laser wavelengths entirely different from those used according to the present invention. Thus, it is absolutely incorrect for the Examiner to assert, as he does at page 10 of the Examiner's Answer, that the present invention is "the predictable use of prior art elements". That might well be said about Navarro, but it cannot be said about the present invention which parted company with Navarro and took an entirely different path which the prior art had warned against. This is the furthest thing from a "predictable use".

The Significance of the Wavelengths Chosen By Others

The uniform activity of others in the art, prior to the present invention, in using wavelengths coming within the range set forth in Navarro, as set forth in Exhibits A-E to the Hennings Declaration, is further confirmation of the fact that the present invention is a departure from the prior art and is what the prior art taught against. The Fan/Rox-Anderson article also notes this departure at page 209.

The Examiner's refusal to give weight to the compelling evidence discussed herein is contrary to applicable law which requires that all evidence be given consideration, In re Sullivan, 84 USPQ2d 1034 (Fed. Cir. 2008).

III. CONCLUSION

The rejection of claims 26-34 is in error and should be withdrawn.

Fees

The Commissioner is authorized to charge Orrick's Deposit Account No. **15-0665** for any fees required and credit any overpayments to said Deposit Account No. **15-0665**.

Respectfully submitted,

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